

Appl. No. : 10/768,200  
Filed : January 30, 2004

### REMARKS

By way of summary, Claims 1-23 were rejected. Applicant has amended Claims 1-7, 10 and 14-21. Applicants have added new Claim 24. Support for new Claim 24 can be found at paragraph [0032] in the specification. Thus, Claims 1-24 are currently pending.

#### Response to Rejection of Claims 1-23 Under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected Claim 1-23 as indefinite under 35 U.S.C. § 112, second paragraph. The Examiner found that Claims 1 and 14 defined the ingredients of the composition in units "mg/kg/day." Applicant has amended Claims 1-7 and 14-20 to specify that the ingredient (e.g., zinc cation) is administered in an amount based on "mg/kg/day." Therefore, Applicant requests that the Examiner withdraw this rejection and pass the claims to allowance.

The Examiner also rejected Claims 10 and 21 as vague and indefinite by the use of the phrase "said treatment is also for hypertension and/or high cholesterol." Applicant has amended Claims 10 and 21 and request that the Examiner withdraw the rejection and pass the claims to allowance.

#### Response to Rejection of Claims 1-23 Under 35 U.S.C. § 103

The Examiner rejects Claims 1-23 as obvious under 35 U.S.C. § 103(a) as unpatentable over Hwang et al. (Diabetes, Obesity and Metabolism, March 2002) in view of Song (US 5,834,032). The Examiner cited Hwang et al. as disclosing the treatment of obese diabetic rats with zinc and arachidonic acid. The Examiner combined this reference with Song which discloses the treatment of diabetes with zinc in combination with arachidonic acid or cyclo-Hispro. Thus, the Examiner found that it would have been obvious to treat a diabetic subject, including an obese diabetic subject, with zinc in combination with cyclo-Hispro or arachadonic acid.

Both Hwang et al. and Song fail to disclose the optimum amount of zinc necessary to reduce body weight. Hwang et al. disclose administering a composition of zinc and arachidonic acid in drinking water containing 10 mg/L of zinc. As described in Hwang et al., the lowest water intake of rats was  $182.9 \pm 12.4$  mL/kg BW/day, which corresponds to the rats being administered 1.829 mg/kg/day of zinc. Thus, Hwang et al. fail to disclose the limitation of

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Claims 1 and 14 that zinc is "administered to the mammal in an amount from about 0.01 to about 1.4 mg/kg/day."

Song also discloses that diabetic rats can be treated with drinking water solutions containing 10 mg/L of zinc. In Table 4, Song discloses that diabetic rats treated with combinations of zinc and arachidonic acid intake no less than  $398 \pm 36 \mu\text{L water/g BW/day}$ , corresponding on average to treating diabetic rats with 3.98 mg/kg/day of zinc. In Table 5, Song discloses that diabetic rats are treated with combinations of zinc and cyclo-Hispro with no less than  $373.3 \pm 47.7 \mu\text{L water/g BW/day}$ , corresponding on average to treating diabetic rats with 3.73 mg/kg/day in combination with cyclo-Hispro. Thus, Song also fails to disclose the limitation that zinc is "administered to the mammal in an amount from about 0.01 to about 1.4 mg/kg/day."

Moreover, the range recited in Claims 1 and 14 provides a method of reducing body weight that is nonobvious over the combination of Hwang et al. and Song. Hwang et al. disclose that their treatment, which includes administration of amounts of zinc that exceeds the range recited in Claims 1 or 14, did not affect body weight. See Hwang et al., page 129, left column, lines 14-17. Similarly, Song also discloses administration of amounts of zinc in excess of the range recited in the claims. Song discloses in Table 3 that diabetic rats treated with such amounts of zinc and cyclo-Hispro increased body weight by  $34.8 \pm 8.3 \text{ g}$ . Thus, Song fails to disclose that zinc and cyclo-Hispro can be used to reduce body weight. Thus, neither reference teaches a method of reducing body weight, as presently claimed. A person having ordinary skill in the art would not use the combination of references as a method to reduce body weight because both references fail to teach or suggest that zinc in combination with cyclo-Hispro or arachidonic acid causes weight loss in overweight or obese mammals.

Applicant has unexpectedly discovered that by keeping the amount of zinc administered within the recited range, body weight can be reduced. In paragraph [0043] of the Applicant's specification, the advantages of the use of zinc in the treatment are discussed. However, the specification makes clear that "excessive zinc supplementation may aggravate obesity by increasing gene expression and adipocyte growth." The amounts of zinc cation disclosed by Hwang et al. and Song were not the optimum amounts to control body weight, particularly when used in conjunction with arachidonic acid or cyclo-Hispro. Applicant has discovered that excess

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dosage of zinc cation may actually inhibit the treatment of obesity and that "balanced zinc nutrition is very important in the control of body weight in both animals and humans." See page 8, line 25. As such, the optimal medicament to reduce body weight by the presently claimed inventions represents an inventive step over the combination of Hwang et al. and Song.

Claims 2-13 depend from Claim 1 and Claims 15-24 depend from Claim 14. These dependent claims further define the invention defined in Claim 1. Claims 2-13 and 15-24 are patentably distinguished over the cited claims and secondary references for at least the reasons set forth above with respect to Claims 1 and 14, as well as for novel and nonobvious features recited therein.

Therefore, Applicant requests that the Examiner withdraw the rejection of Claims 1-23 and earnestly solicit the allowance of Claims 1-24.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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